

Application No. 10/505,232

IN THE DRAWING:

Please substitute the replacement sheet for Figure 1 submitted herewith for the original sheet containing Figure 1.

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REMARKS

Claims 1-22 are pending herein.

At the Examiner's request, the specification has been reviewed and amended to correct typographical and grammatical errors and for matters of form. In addition, an Abstract has been provided.

Fig. 1 of the drawing has been amended to add the designation "PRIOR ART."

Claims 1-10 were rejected as anticipated by Lofley et al. (WO 90/13280) and claims 1, 2, 8, 11-14 and 16 were rejected as obvious over Lofley et al. Claims 15 and 17-22 were rejected as obvious over Lofley et al. in view of the Gordon U.S. patent No. 4,494,581. Reconsideration of each of these rejections is respectfully requested.

The pending claims are directed to a urine sample collection device. The problem to be solved by the present invention is to provide such a device in which a mid stream urine sample can be automatically taken without active intervention or control by the user. In this respect, the device, which is usable by both male and female users, should enable users to locate the device by the urethra and then urinate freely without consideration of having to temporarily halt the urine flow, and with the mid stream urine sample itself being directly and automatically taken without contamination.

It should be noted that the form of the device provides for a through flow route from the urethra of the user through the elongate tubular member to the open end thereof. Thus, a user can urinate freely without consideration of having to temporarily halt the urine flow with excess urine passing out of the open end. In addition, by providing a flow director as recited in paragraph (d) of claim 1, located in this way and formed to direct urine past the opening, the

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early urine flow is directed past the opening such that it is not collected, thereby avoiding contamination. Thereafter, the urine flow becomes so great that the function of the flow director is not fully functional and urine flows into the opening and is collected as a sample in the urine collection container. Consequently, automatic collection of a mid-stream urine sample is provided.

The Examiner argues that features a) to d) of claim 1 are all disclosed in Lofley et al. (WO 1990/013280). Applicant courteously contends that this is incorrect. Lofley et al makes no mention of including a flow director located within the tubular member to direct urine past the opening. Looking at figure 1 of Lofley, the disclosed device uses a manually operated air-lock system (gate valve 101) to control whether urine will flow into the container 17. Thus, there is no disclosure of a passage whereby urine flowing in the tube 12 can flow into the mounted container 17. Instead, urine flowing in the tube 12 will only flow into the mounted container when the gate valve is operated. In addition, it is clearly stated on page 13, lines 9-12 that the lug portion 102, opposite sampling passage 19, has the function of deflecting a portion of urine flowing through the discharge passage 16 into sampling passage 19 and into container 17 when valve 101 is open. It can be seen that this embodiment therefore does not contain a flow director which is located within the tube 12 to direct urine past the opening. It discloses the exact opposite. Looking at figure 2, the air-lock system of gate valve 101 is replaced by a manually rotatable valve 25. It is therefore apparent that this embodiment also does not contain a passage, whereby urine flowing in the tube 12 can flow into the mounted container 17 without operation of a valve and also does not contain a flow director located within the tubular member to direct urine past the opening. The same can be said in relation to the embodiment of figures 20A to

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20G where there is no disclosure of the additional feature of a flow director located within the tubular member at or adjacent the opening and formed to direct urine past the opening. It is noted that a flow director directing urine past the sampling passage would have no purpose or benefit in Lofley et al.

Thus, the disclosure of Lofley et al. is completely different from the present invention where there is first a coupling means which has a passage extending therethrough which meets the opening, whereby urine flowing in the tubular member can flow therefrom into a mounted container; and second a flow director located within the tubular member at or adjacent the opening, which flow director is formed to direct urine past the opening. Lofley et al requires the use of a valve to enable urine to flow from the tubular member into a mounted container and has a lug portion having the exact opposite function to the flow director of the present invention.

The reason for the form of the flow director of the present invention is stated on page 3, lines 20-23 of the published PCT application, that is to say the flow director has a form to automatically enable the collection of a midstream urine sample by directing urine which is not from the midstream towards the open end of the tubular member and direct midstream urine into the urine collection container.

It is therefore submitted that claim 1 currently on file is clearly novel relative to the disclosure of Lofley et al.

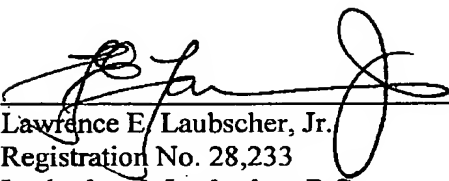
With regard to the obviousness rejections including those based on Gordon, since the rejected claims are dependent on claim1 which it is submitted is allowable, then these rejected claims should also be allowable.

Allowance of claims 1-22 is respectfully requested.

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Respectfully submitted,

November 9, 2006

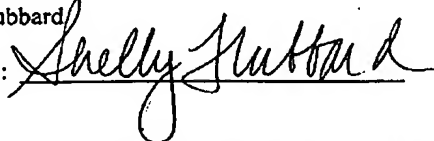

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